patient an amount of the immunogenic composition according to claim 9 sufficient to effect said induction.

12. (Amended) A method of inducing an immune response in a patient comprising administering to said patient an amount of the immunogenic composition according to claim 10 sufficient to effect said induction.

IN THE ABSTRACT:

Substitute the Abstract of the Disclosure submitted herewith for that originally filed.

REMARKS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The specification has been amended at Table 2 (page 21) to correct the sequences given for the two entries given for epitope location 117-128 (HLA restriction elements B17,B37). Both now properly read TQGYFPDWQNYT. That the originally presented sequences were in error and that the sequence now presented is correct is evident from the attached relevant portions of the HIV MOLECULAR IMMUNOLOGY DATABASE 1999 - attention being particularly

directed to page I-D-184, upper right corner, Epitope # 39 (HLA B17,B37) which reads "TQGYFPDWQNYT". A hand-amended copy of Table 2 showing the corrections introduced by the newly presented Table 2 is attached. The specification has been further amended to include a new Sequence Listing that should be substituted for that previously filed. The new Sequence listing corrects the error that has been noted in SED ID NO:4 (which corresponds to the two entries in Table 2 referenced above). Entry of the new Sequence Listing does not raise the issue of new matter as the sequence information contained therein is presented in the application as originally filed, the sequence now presented for SEQ ID NO:4 representing a correction of an obvious error, as evidenced by the above-referenced submission herewith of relevant portions of the HIV MOLECULAR IMMUNOLOGY DATABASE 1999. The computer readable copy of the Sequence Listing submitted herewith is the same as the attached paper copy of that Listing.

The claims have been revised to define the invention with additional clarity. The amendment results in the adoption of language considered by the Examiner to be appropriate (see comments below). That the claims have been revised should not be construed as an acknowledgement that Applicants agree with any position expressed by the

Examiner. Rather, the non-narrowing revision is made merely to advance prosecution.

As regards the Examiner's requirement for restriction, reconsideration is again requested. In responding to Applicants' prior request, the Examiner merely states that "each application is charged a flat fee regardless of the number of sequences, the examination of which uses office resources." The Examiner's attention is directed to MPEP 803.04 which makes it clear that a "reasonable number" of sequences are to be considered in a single application and that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." The Examiner has provided nothing to indicate why the present application should not be entitled to the treatment indicated in the MPEP as appropriate and acknowledged by the MPEP as not being unduly burdensome on the Office. Indeed, the nature of the present invention (which relates, at least in part, to a composition comprising a mixture or linear assay of peptides (see claim 9)) virtually necessitates the consideration of more than 1 sequence. Accordingly, the Examiner is again urged to reconsider the requirement for restriction. Applicants reserve the right to file a Petition under 37 CFR 1.144. The Examiner's objection to claims 9, 11 and 12, on the

basis that they contain non-elected sequences, is noted (explanation as to why claim 12 is included in the objection is requested). The Examiner is urged to hold the objection in abeyance, in view of the above further request for reconsideration.

On page 2 of the Action, the Examiner objects to the disclosure on the basis that the copy of Table 3 submitted by facsimile with the prior response is unclear. A further copy of that Table is provided herewith.

In response to the Examiner's objection to the Abstract originally filed, a substitute Abstract is provided herewith on a separate sheet.

Claims 9-12 stand rejected under 35 USC 101 as allegedly lacking utility. Withdrawal of the rejection is believed to be in order in view of the above-noted claim revisions and comments that follow.

At the outset, the Examiner's attention is directed to the fact that the claims have been revised so as to be drawn to an immunogenic composition, and method of using same. The Examiner acknowledges that the disclosure is enabling for such a composition (see remarks below responsive to the rejection of claims 9-12 under 35 USC 112, first paragraph). As the Examiner's arguments relating to HIV vaccines are understood, it is believed

that this revision address the Examiner's concerns. Nonetheless, the following further comments are offered.

In rejecting the claims as lacking utility, the Examiner contends that the specification fails to teach or describe the use of the claimed invention as a vaccine. No basis for this assertion is seen The disclosure describes the peptides to be used, the formulation of such peptides into a composition (e.g., see pages 12 and 13) and routes of administration (see page 16). Further, the application includes a working example demonstrating achievement of an immune response in both HIV infected and in non-infected individuals. Accordingly, it is submitted that the subject disclosure is in no way deficient.

The Examiner also makes reference to certain difficulties involved in development of an HIV vaccine. Indeed, it is with the problems associated with HIV in mind that the present invention was made. This will be apparent from a review of the Background and Detailed Description sections of the subject application.

In view of the above, it will be clear that the utility requirements of 35 USC 101 are fully met. Reconsideration is thus requested.

Claims 9-12 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of

the rejection is submitted to be in order in view of the above-noted claim amendments and further in view of the comments that follow.

Claim 9 and 10 as now presented (from which claims 11 and 12 depend) are drawn to immunogenic compositions. The Examiner expressly acknowledges such compositions to be enabled by the disclosure. Accordingly, the revision is believed to moot the Examiner's concerns. Reconsideration is requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made**."

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

9. (Amended) [A vaccine] An immunogenic composition comprising a mixture or linear array of peptides, or variants thereof, selected from the peptides set forth in Table 3 (SEQ ID NOs: 14-42) and linear arrays set forth in Table 4 (SEQ ID Nos:43-94).

10. (Amended) [A vaccine] An immunogenic composition comprising the peptide of SEQ ID NO:39.

11. (Amended) A method of inducing an immune response in a patient comprising administering to said patient an amount of the [vaccine] immunogenic composition according to claim 9 sufficient to effect said induction.

12. (Amended) A method of inducing an immune response in a patient comprising administering to said patient an amount of the [vaccine] immunogenic composition according to claim 10 sufficient to effect said induction.

Table 2. **Proportion of each of the four populations that would be predicted to present peptides to the immune system**

Population	HLA Restriction Elements Chosen	HIV Protein	Epitope Location	Epitope
a) African Americans	A2, A3, A11, B35	nef	73–82	QVPLRPMTYK
	A28, B14	gp41	583–592	VERYLKDQQL
	A30, B8	gp41	844–863	RRIRQGLERALL
	B17, B37	nef	117–128	TQGYFPDWQNYT
	Cw4	gp120	576–383	(S)FNCGGEFF
(Proportion of African Americans expected to present these 5 epitopes is 92.3%)				
b) USA Caucasians	A2, A3, A11, B35	nef	73–82	QVPLRPMTYK
	A30, B8	gp41	844–863	RRIRQGLERALL
	B7	gp120	302–312*	RPNNNTRKSI
		nef	126–138*	NYTPGPGVRYPLT
	B12	p24	169–184	IPMFSALSEGATPQDL
(Proportion of USA Caucasians expected to present these 4 epitopes is 90.2%)				
c) North American Indians	A2, A3, A11, B35	nef	73–82	QVPLRPMTYK
	A24	gp41	584–591*	YLKDQQL
		nef	120–144*	YFPDWQNYTPGPGIRYPLTFGWCYK
	A31	gp41	770–780	RLRDLLLIVTR
(Proportion of North American Indians expected to present these 3 epitopes is 96.4%)				
d) Thais	A2, A3, A11, B35	nef	73–82	QVLRPMTYK
	A24	gp41	584–591*	YLKDQQL
		nef	120–144*	YFPDWQNYTPGPGIRYPLTFCGWCYK
(Proportion of Thais expected to present these 2 epitopes is 93.6%)				
e) African Americans USA Caucasians North American Indians Thais	A2, A3, A11, B35	nef	73–82	QVPLRPMTYK
	A28, B14	gp41	583–592	VERYLKDQQL
	A30, B8	gp41	844–863	RRIRQGLERALL
	B17, B37	nef	117–128	TQGYFPDWQNYT
	Cw4	gp120	376–383	(S)FNCGGEFF
	B7	gp120	302–312*	RPNNNTRKSI
		nef	126–138*	NYTPGPGVRYPLT
	B12	p24	169–184	IPMFSALSEGATPQDL
	A31	gp41	770–780	RLRDLLLIVTR
	A24	gp41	584–591*	YLKDQQL
		nef	120–144*	YFPDWQNYTPGPGIRYPLTFCGWCYK
(Proportions of African Americans, USA Caucasians, North American Indians, and Thais expected to present these 9 epitopes are 95.4%, 97.5%, 99.4%, and 97.2%, respectively)				

*The criteria upon which choices among peptides should be made are not yet known. It may be important to choose peptides that have been reported to be immunogenic in non-progressors to AIDS or that have been reported to induce immunodominant anti-HIV T-cell responses.